

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: Joel S. Hochman, et al

Ser. No.: 10/007,393

Filed: October 26, 2001

For: SYSTEM AND METHOD FOR TRANSDUCING, SENSING OR AFFECTING VAGINAL OR BODY CONDITIONS, AND/OR STIMULATING PERINEAL MUSCULATURE AND NERVES USING 2-WAY WIRELESS COMMUNICATIONS

Examiner: Charles A. Marmor

Group: 3736

Commissioner for Patents
PO Box 1450
Alexandria VA 22313

I, Kurt R. Wharton MD, declare as follows:

1. I received an A.B. Degree in Physiology and Anatomy from the University of California at Berkeley in 1980. I received my Medical Degree from Boston University School of Medicine in 1984. After completing an Internship in Obstetrics and Gynecology at Mount Zion Hospital and Medical Center in 1985, I was a Resident in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco from 1985 through 1987. I served as Administrative Chief Resident during the academic year ending in 1988. I am currently Chairman, Department of Obstetrics and Gynecology at Alta Bates Summit Hospital in Berkeley, California. Additionally, I am the Site Director for Resident Education and I hold the Academic position of Associate Clinical Professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco. I am a Fellow of the American College of Obstetrics and Gynecology and I am Board Certified by the American Board of Obstetrics and Gynecology.

2. I am familiar with the subject matter of the above-identified application. Additionally, I have reviewed the U.S. Patent Publication 2002/0010390, Guice, et al.
3. Based upon my training and professional expertise in Human Physiology, Obstetrics, Gynecology and Women's Health, I can state that no reference would be given to the Guice Patent by individuals attempting to develop biomedical systems intended to transduce vaginal conditions, affect vaginal or body conditions, or stimulate perineal neuromuscular tissues.
4. By recognized clinical medical standards, the Guice Patent is a Patent for an animal implant. The Patent clearly identifies telesensor implant units intended for implantation in the ear, vagina, rectum, throat, nostril or subcutaneous tissues. The telesensors may also be implanted percutaneously. Paragraph 0164 of the Guice Patent states "the telesensor implant, which may be exposed to animal tissue or fluids, should be biocompatible, and in many cases, should promote the ingrowth of tissue to help anchor the telesensor implant in the desired implant location." Obviously, such a device is unacceptable and inappropriate for the human vagina.
5. Examples of intravaginal medical devices that are not implants include contraceptive diaphragms, pessaries used to treat genital organ prolapse, and medical delivery systems such as the contraceptive NuvaRing and the estrogen releasing Estring. Such devices are placed into the vagina by the patient or healthcare provider and easily removed by the patient or healthcare provider. No surgery, tools or adhesives are required, as is the case with the Guice implant. In contrast to Guice, the Patent requested by Athena allows for the development of temporarily insertable medical devices. Guice on the other hand actually refutes the use of non-implanted devices (see for example [34]).
6. In summary, the Guice implant device is in no way appropriate or acceptable for use in the human vagina. Individuals developing medical devices for temporary placement within the human vagina would not consider the Guice reference.
7. I hereby declare that all statements made herein are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code, and that such willful, false statements may jeopardize the validity of this application, the patent which issues thereon, or any patent to which this verified statement is directed.



Kurt R. Wharton, M.D.

11/22/04

Date